

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

The Office Action Summary correctly indicates that claims 1-10 are pending in the application and under consideration. Claims 1-8 have been indicated as allowable. Claims 9-10 stand rejected.

Claims 29-31 are added. Support for claim 29 can be found in the specification and original claims, for example at page 13, line 11. Support for claim 30 can be found in the specification and original claims, for example in the paragraph bridging pages 20 and 21. Support for claim 31 can be found in the specification and original claims, for example at page 12 and in the paragraph bridging pages 20 and 21.

No prohibited new matter has been introduced by way of the above amendments. Applicants reserve the right to file a continuation or divisional application on subject matter canceled by way of this Amendment.

**Rejections under 35 U.S.C. § 102*****Claim 9***

Claim 9 stands rejected under 35 U.S.C. § 102 as allegedly anticipated by Korn et al. (Accession No. A98448, September 27, 1997) It has been alleged that Korn et al. describes a sequence having bases 180-199 that align identically with bases 1164-1183 of SEQ ID NO:4084. The rejection is respectfully traversed.

Although the cited sequence appears to comprise a sequence of 20 contiguous nucleotides also found in SEQ ID NO: 4084, the cited sequence does not “consist of at least 20 contiguous nucleotides of . . . SEQ ID NO: 4084 . . .” as recited by claim 9. Claim 9

recites "A probe comprising a nucleotide sequence consisting of at least twenty contiguous nucleotides of a nucleotide sequence selected from the group consisting of: (a) SEQ ID NO: 4084; (b) a complement of SEQ ID NO: 4084; and (c) an RNA of (a) or (b), wherein U is substituted for T."

Furthermore, claim 9 is directed to a probe. The probe of claim 9 can comprise elements in addition to the recited nucleic acid sequence, but only elements that are not inconsistent with being a probe as described in the specification at pages 19-20. A nucleic acid containing a substantial amount of sequence not in SEQ ID NO: 4084 in addition to the recited sequence would be inconsistent with its function as a probe. The sequence taught by Korn *et al.* includes a substantial amount of nucleic acid sequence not in SEQ ID NO: 4084. Thus, the cited reference does not describe every limitation of claim 9. Moreover, as the reference appears to be an otherwise unpublished submission of an EST, there is no teaching or suggestion in Korn *et al.*, that would lead one to select a probe comprising a nucleic acid sequence consisting of the 20 nucleic acids that appear to align with a portion of SEQ ID NO: 4084.

#### ***Claim 10***

Claim 10 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Ziegelin *et al.* (Accession No. AJ011592, October 01, 1998). It has been alleged that, because residues 1144-1185 of the cited sequence encode 14 amino acids found in SEQ ID NO 9036 the claim is anticipated. The rejection is respectfully traversed.

First, it is noted that the date of the reference is less than one year prior to the priority date of the present application, therefore 35 U.S.C. § 102(b) is not applicable. Second, Zeigelin *et al.* does not anticipate the present invention, because, Zeigelin *et al.* does not teach every element of the claimed invention arranged as described in the claim.

Ziegelin et al. teaches a sequence encoding a polypeptide that is clearly not a *Bacterioides fragilis* polypeptide as recited by claim 10. There is no teaching or suggestion to cut and isolate any portion of the cited sequence in such a way as to encode a polypeptide fragment falling within the definition of a *Bacterioides fragilis* polypeptide as defined in the specification and as recited in claim 10.

Furthermore, the Official Action does not allege and does not show that the cited sequence would be hybridizable to a nucleic acid having a nucleotide sequence selected from the group consisting of: SEQ ID NO: 4084; a complement of SEQ ID NO: 4084; and an RNA of (a) or (b), wherein U is substituted for T as required by claim 10. There is less than 70% identity of bases between SEQ ID NO: 4084 bases 1282-1323 and bases 1144-1185 of the cited sequence as a consequence of different codon usage.

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agtgaccttcgtgaatccggtgcaatcgagcaggatgccgat  bases 1282-1323 of SEQ ID NO: 4084
xxx||xxxxx|||||||x||x|||||x|||||||x||x||x
tcagatttacgtgaatcaggagcaattgagcaggacgcagac  bases 1144-1185 of AJ011592
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Furthermore, the referenced sequence contains substantial sequence with less similarity to SEQ ID NO: 4084. There is no teaching or suggestion in the reference that would direct one to modify the referenced sequence so as to meet the hybridization requirement. Thus, the cited art does not describe every element of claim 10.

Applicant respectfully submits that for at least the foregoing reasons, the rejections of claims 9 and 10 under 35 U.S.C. § 102 are improper. Accordingly, Applicant respectfully requests withdrawal of the rejections.

### **Rejections under 35 U.S.C. § 112**

Claim 10 stands rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter that was not described in the specification in such a manner as to

reasonably convey to one skilled in the art that Applicant had possession of the claimed invention at the time the application was filed.

Applicant respectfully submits that the description of claim 10 that is set forth on page 4 of the Official Action does not reasonably reflect the actual language of claim 10. Claim 10 recites an isolated nucleic acid encoding a *B. fragilis* polypeptide of at least 10 consecutive amino acids of SEQ ID NO: 9306, wherein the nucleic acid is hybridizable to a nucleic acid having a nucleotide sequence selected from the group consisting of: (a) SEQ ID NO: 4084; (b) a complement of SEQ ID NO: 4084; and (c) an RNA of (a) or (b), wherein U is substituted for T. Thus, the nucleic acid of claim 10 does not encompass any sequence capable of hybridizing to a recited sequence, but must also be an isolated nucleic acid encoding a *B. fragilis* polypeptide of at least 10 consecutive amino acids of SEQ ID NO: 9306. A large number of such sequences can be determined in the form of appropriate length fragments of SEQ ID NO 4084, which is disclosed in the specification. Further, contrary to the assertion at page 4 of the Official Action, hybridization conditions are defined and described in detail in the specification, for example in a paragraph bridging pages 20-21. Moreover, knowledge of the structural requirements associated with hybridization was well understood in the art at the time the application was filed. Thus, a representative number of the claimed genus of isolated nucleic acids is adequately described in the specification.

The Response to Comment 5 of the Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 F.R. 1099, 1101 (2001) states that the purpose of the Guidelines is to clarify for the examining corps the criteria needed to satisfy the written description requirement. The Response to Comment 5 further directs the reader to the "Synopsis of Application of Written Description Guidelines" (examiner training materials available on-line at

<http://www.uspto.gov/web/menu/written.pdf>) for examples applying the Guidelines to various fact situations. Example 9 of the Synopsis of Application of Written Description Guidelines demonstrates that the United States Patent Office, in considering a hypothetical application having a claim such as claim 10 has determined that such claims in an application analogous to the present application satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

The specification discloses an open reading frame SEQ ID NO: 4084 that encodes a polypeptide SEQ ID NO: 9306. By simple logical derivation, fragments of SEQ ID NO: 4084 encoding at least 10 consecutive amino acids of SEQ ID NO: 9306 can be identified. Such fragments would certainly be hybridizable to a nucleic acid having a nucleotide sequence selected from the group consisting of: (a) SEQ ID NO: 4084; (b) a complement of SEQ ID NO: 4084; and (c) an RNA of (a) or (b), wherein U is substituted for T. Additional sequences encoding at least 10 consecutive amino acids of SEQ ID NO: 9306 can be determined by reference to the well known genetic code. One skilled in the art would not expect substantial variation among the species encompassed within the claims, because the hybridization conditions set forth in the claim yield structurally similar nucleic acids. Under such circumstances, Example 9 of the Synopsis of Application of Written Description Guidelines concludes that a representative number of species is disclosed since the hybridization conditions together with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that Applicant was in possession of the claimed invention.

Therefore, at least by the reasoning presented in the training materials of the United States Patent Office, the presently claimed invention is adequately described in the

specification. Accordingly, withdrawal of the rejection of claim 10 under 35 U.S.C. § 112, first paragraph, written description requirement is respectfully requested.

### CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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